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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/031,365      | 02/19/2002  | Gary Lock            | 5625                | 6892             |

6858 7590 07/29/2004

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EXAMINER

MUTSCHLER, BRIAN L

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1753

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                |                             |  |
|------------------------------|--------------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/031,365  | Applicant(s)<br>LOCK ET AL. |  |
|                              | Examiner<br>Brian L. Mutschler | Art Unit<br>1753            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-23 and 32, drawn to an electrode formation and a method for measuring an electrokinetic parameter.
  - II. Group II, claim(s) 24-28, drawn to a method for maintaining viability of a particle.
2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims of Group II recite a method for maintaining the viability of a particle, which requires the presence of a viable particle as well as steps to control the process to maintain the viability of the particle. Group I differs from Group II because Group I only provides an apparatus and method for measuring an AC electrokinetic parameter. Maintaining the viability of a particle requires additional structural features to control the conditions during the performance of the process.
3. During a telephone conversation with Ms. Mary Breiner on July 23, 2004, a provisional election was made without traverse to prosecute the invention of Group I,

claims 1-23 and 32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Comments***

5. It is noted that several claims recite limitations stating that the measurement electrode array is connectable to measurement means, e.g., see claim 3. This claim language does not positively recite the presence of measurement means or any other structural limitation related to the measurement electrode array. Almost any electrode array is connectable to something. Therefore, these limitations are regarded as intended use and have little weight since the electrodes of the prior art are capable of being connected to such measurement means.

#### ***Drawings***

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “24” has been used to designate both a connector and a coil (see Figure 1a and page 9, lines 17 and 26).

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **64** and **66** (Figure 6); **25** (Figure 9).
8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: **88** (page 16, line 14); **94** (page 16, line 35; page 17, lines 4 and 8); and **132** (page 18, lines 13 and 21).
9. Corrected drawing sheets, or amendment to the specification to add the reference character(s) in the description, are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Specification***

10. The disclosure is objected to because of the following informalities:
  - a. On page 20 at lines 16-17, please identify the country of the co-pending application.Appropriate correction is required.

***Claim Objections***

11. Claims 13, 14, 19, and 21 are objected to because of the following informalities:

- a. In claim 13 at line 2, change "TWD" to --traveling wave dielectrophoresis (TWD)--.
- b. In claim 13 at line 5, please insert --of TWD electrodes-- after "said two or more arrays".
- c. In claim 14 at line 5, please change "the array" to --the measurement electrode array--.
- d. In claim 19 at line 3, please change "DEP" to --dielectrophoresis (DEP)--.
- e. In claim 19 at line 3, please change "TWD" to --traveling wave dielectrophoresis (TWD)--.
- f. In claim 21 at line 3, it appears that the term "proportion" should be changed to --portion--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-23 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "AC electrokinetic-related parameter" in line 7. This limitation is indefinite because the parameters that are considered to be AC electrokinetic-related parameters are not apparent. What constitutes an AC electrokinetic-related parameter? The specification identifies several parameters such as temperature, impedance, etc. However, the scope of parameters encompassed by the phrase is indefinite. Is the conductivity or polarity of the solution an AC electrokinetic-related parameter? What other parameters are considered AC electrokinetic-related parameters? The parameters measured by the apparatus and method should be more clearly defined. The phrase also appears in claims 16-19 and 23. The same applies to dependent claims 2-18, 20-22, and 32.

Claim 18 recites the limitation "the adjustment means is selective application of a protein or of a protein and a protein-binding ligand" in lines 3-5. This limitation is indefinite because "adjustment means" is a structural feature and "selective application" is a procedure. Therefore, the structure of the adjustment means is indefinite.

### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1753

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-4, 6, 10-16, 19-23, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al. (U.S. Pat. No. 6,294,063).

Regarding claims 1, 15, 19, and 23, Becker et al. disclose an apparatus and method for use in an AC electrokinetic effect cell comprising a substrate and a plurality of driving electrodes and a plurality of measurement electrodes (figs. 1 and 3-5; col. 11, lines 57-61).

Regarding claims 2-4, 6, 10-12, 20, 22, and 32, the measurement electrodes comprise a plurality of electrodes **19** connectable in pairs to measure impedance (fig. 3; col. 10, lines 10-24; col. 11, lines 57-61).

Regarding claim 13, the driving electrodes comprise an array of individually addressable array of electrodes **18** that are driven with AC signals to move particles through the cell (col. 13, lines 37-49).

Regarding claim 14, the array of driving electrodes **18** and the array of measurement electrodes **19** overlap and are separated by an insulating film (fig. 4; col. 12, lines 23-41).

Regarding claim 15, the device may comprise a top wall (second substrate) spaced apart from the first substrate (col. 14, lines 55-65).

Regarding claims 15, 19, and 23, the device further comprises a signal supply means **25** to generate an AC electrokinetic force and measuring means **23** associated with the impedance sensing electrodes **19** (col. 13, line 29 to col. 14, line 13).



Regarding claim 16, the device comprises means to manipulate the particles in response to the detection electrodes **19** (col. 13, line 50 to col. 14, line 13).

Regarding claim 21, the measuring means **23** is connectable to the sensing electrodes **19** (fig. 3; col. 14, lines 6-13).

Since Becker et al. teach all of the structural limitations of claims 1-4, 6, 10-16, 19-22, and 32, and all of the method limitations of claim 23 as recited in the instant claims, the reference is deemed to be anticipatory.

16. Claims 1-4, 6-8, 15-16, 18, 19, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatschek et al. (U.S. Pat. No. 5,489,515).

Regarding claims 1, 15, 19, and 23, Hatschek et al. disclose a method and device for analyzing cells in an electrokinetic effect apparatus comprising a substrate **54**, a plurality of dielectrophoresis electrodes connected to an AC generator, and a measurement electrode array (figs. 1-3; col. 2, lines 41-53; col. 3, lines 49-59; col. 9, lines 1-29).

Regarding claims 2-4 and 6-8, the measurement electrodes comprise a pair of electrodes, measuring electrode **56** and control electrode **57**, for measuring the pH of the solution (col. 7, lines 7-64).

Regarding claim 7, the pair of electrodes **56**, **57** may be separated by piece of silicon **68** (col. 7, line 65 to col. 8, line 7).

Regarding claim 8, the measurement electrode may comprise a layer of silver chloride or calomel, which are both inorganic salts (col. 5, lines 10-15).

Regarding claim 15, the device further comprises a second substrate (cover **73**) and a signal supply means to generate an AC electrokinetic force (fig. 1; col. 9, lines 1-29).

Regarding claims 15, 16, 19, and 23, a measuring and control circuit **80** determines the pH value measured by the measurement electrodes and controls the control electrode **57** to adjust the pH (col. 10, lines 30-64).

Regarding claim 18, the device measures the chemical composition of the fluid by measuring the amount of acid released by the cells (col. 10, lines 30-64).

Since Hatschek et al. teach all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 1-3, 5, 9, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryning et al. (U.S. Pat. No. 6,537,433) in view of Mathies et al. (U.S. Pat. No. 6,261,431).

Regarding claims 1 and 15, Bryning et al. disclose a method and apparatus for use in an AC electrokinetic effect cell comprising a channel, a plurality of electrodes

**140a, 140b** for the application of an AC electrokinetic force, and temperature measurement sensors (col. 7, lines 22-54; col. 14, line 56 to col. 15, line 3).

Regarding claim 2, the plurality of electrodes s connectable to measurement means to measure the temperature of the liquid in the vicinity of the electrodes (col. 14, line 56 to col. 15, line 3).

Regarding claims 15, the device comprises an AC generator and measuring means to measure the temperature (col. 7, lines 22-54; col. 14, line 56 to col. 15, line 3).

Regarding claims 16 and 17, the device further comprises a Peltier cooling device for controlling the temperature (col. 14, line 56 to col. 15, line 3).

The device of Bryning et al. differs from the instant invention because Bryning et al. do not disclose the following:

- a. A substrate, as recited in claim 1.
- b. A measurement electrode array, as recited in claims 1, 3, 5, 9, and 15.
- c. The measurement electrode array is a single elongated electrode, as recited in claims 5 and 9.
- d. A second substrate, as recited in claim 15.

Mathies et al. discloses a similar channel device that is formed within a substrate and has a second substrate forming the top of the channel (fig. 10C). The device further comprises electrodes for manipulating the sample and temperature sensors (col. 3, lines 27-35). The temperature sensors comprise thermocouples and platinum resistance temperature sensing devices (col. 3, lines 27-35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the channel of Bryning et al. to use a supporting substrate and a cover substrate as taught by Mathies et al. because the substrates would provide structural support to the channel and simplify transport and handling of the channels, and a second substrate covering the channel would prevent the evaporation of the liquid within the channel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the temperature sensors of Bryning et al. to use thermocouples, which are single elongated electrodes, as taught by Mathies et al. because thermocouples are simple and efficient temperature sensors commonly used for the purpose of measuring temperature.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

In U.S. Pat. No. 6,437,551, Krulevitch et al. disclose an AC impedance sensor for a microfabricated device.

The following references have been cited in the International Search Report for PCT/GB00/02801. The reference of Holzel is particularly applicable to the instant claims.

Holzel, R., "Electrorotation of Single Yeast Cells at Frequencies Between 100 Hz and 1.6 GHz," Biophysical Journal, Vol. 73, August 1997, p. 1103-1109.

Art Unit: 1753

Milner et al., Dielectrophoretic classification of bacteria using differential impedance measurements," Electronics Letters, Vol. 34, No. 1, 08 January 1998, p. 66-68.


Fuhr et al., "Positioning and Manipulation of Cells and Microparticles Using Miniaturized Electric Field Traps and Travelling Waves," Sensors and Materials, Vol. 7, No. 2, 1995, p. 131-146.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLM  
July 27, 2004

  
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